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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
PARAS JR, PETER

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/348,469	Applicant(s) SMITH ET AL.	
	Examiner Peter Paras, Jr.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-24,26-34, and 41- 42* is/are pending in the application.

4a) Of the above claim(s) *30 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24,26-29,32-34,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment received on 12/10/02 has been entered. Claims 22, 28-32 and 34 have been amended. Claims 43-46 have been cancelled. Claims 22-24, 26-29, 32-34 and 41-42 are under current consideration. Claims 22-24, 26-34 and 41-42 are pending.

Election/Restrictions

Claims 30-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

This application contains claims drawn to an invention, nonelected in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

It is noted that Applicant's amendment of 12/10/02 was directed to a different Examiner. Please direct all future correspondence to Examiner Peter Paras, Jr of Art Unit 1632.

It is further noted that the amendments to claims 22 and 32 do not comply with 37 C.F.R. 1.121. However, such did not affect examination of the claims.

Specification

The previous objection to the disclosure has been withdrawn in view of Applicant's amendment to the specification.

Sequence Compliance

The instant application is now in sequence compliance.

Priority

Applicant's claim of priority to 08/537,765 now US patent 6,150,169 is denied. The parent application fails to fulfill the requirements of 35 U.S.C. 120 by not meeting the requirements of the first paragraph of 35 U.S.C. 112, particularly written description and new matter, necessary to support the claims of the instant application. In particular the claim limitations, added by the amendment of 12/10/02, as follows are not described in the instant specification: a DNA construct comprising the sequence 5' A-P-B-Q-C 3'. See the rejections under 35 U.S.C. 112, 1st paragraph.

Claim Rejections - 35 USC § 112, 1st paragraph

The following New Matter rejection has been necessitated by Applicant's amendments to the claims:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-24, 26-29, 32-34 and 41-42 as amended are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 is directed to a method of inserting a heterologous gene coding sequence into an endogenous gene in a mouse embryonic stem cell genome and expressing said heterologous gene coding sequence, comprising the step of transforming the mouse embryonic stem cell with a DNA construct, wherein the DNA construct lack a promoter, and comprises the sequence: 5' A-P-B-Q-C 3' in which P is an internal ribosome entry site (IRES), Q is the heterologous gene sequence, and A, B, and C are, separately, optional linker sequences, wherein the DNA construct further comprises a polyadenylation signal at the 3' end of Q and a splice acceptor site located 5' of Q.

Claim 32 is directed to a DNA construct comprising the sequence: 5' A-P-B-Q-C 3' in which P is an internal ribosome entry site (IRES), Q is the heterologous gene sequence, and A, B, and C are, separately, optional linker sequences, wherein the DNA construct further comprises a polyadenylation signal at the 3' end of Q and a splice acceptor site located 5' of Q.

The specification provides no implicit or explicit support for a DNA construct comprising the sequence: 5' A-P-B-Q-C 3' in which P is an internal ribosome entry site (IRES), Q is the heterologous gene sequence, and A, B, and C are, separately, optional linker sequences, wherein the DNA construct further comprises a polyadenylation signal at the 3' end of Q and a splice acceptor site located 5' of Q. The specification, on page 6 and throughout, has only provided support for a DNA construct comprising the

sequence 5' X-A-P-B-Q-C-Y 3' but not a DNA construct comprising the sequence 5' A-P-B-Q-C 3' is supported by the specification. Applicants are reminded that it is their burden to show where the specification supports any amendments to the claims. See 37 CFR 1.121 (b)(2)(iii), the MPEP 714.02, 3rd paragraph, last sentence and also the MPEP 2163.07, last sentence.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure* [or point to case law supporting incorporation of such a limitation as in the instant case]".

Applicant's arguments filed 12/10/02 have been fully considered but they are not persuasive. Applicants have argued that in the first full paragraph of page 14, it is

contemplated that the invention includes using a promoterless construct according to the invention and allowing the construct to randomly integrate in a host genome. Applicants point out that on page 11 it is explained that random integration does not require homologous recombination with a target gene and on page 1, where it is discussed that sequences can be inserted into a host genome without limiting to homologous recombination. Applicants submit that it will be absolutely clear to a skilled artisan that in the embodiment of the invention that covers random integration, homologous sequences X and Y are not needed and also that a promoter is not used. Applicants further point to original claims 7 and 8 in support of newly added claim limitations regarding the location of the polyadenylation signal and splice acceptor site. See pages 4-6 of the amendment.

In response, the Examiner asserts that a construct having the sequence 5' A-P-B-Q-C 3' has not been described in the instant specification for reasons cited above. The claimed construct is not a readily apparent variant of 5' X-P-B-Q-C-Y 3' because the specification has not contemplated constructs that lack X and Y. As such, it appears that the discussion of random integration provided by the specification, on page 14, is limited to the construct 5' X-P-B-Q-C-Y 3'. Moreover, the claims of the allowed parent application, 08/537,765 (now US 6,150,169), appear to contradict Applicants arguments regarding random integration, particularly with regards to the presence of X and Y and use of a promoter. See for example, allowed claims 24 and 29, which are directed to methods of inserting a coding gene sequence into the genome of a eukaryotic cell by random integration wherein the construct comprises the sequence 5'

X-A-P-B-Q-C-Y 3', in which X and Y are homologous with separate sequences from the same donor cell genome and comprise the elements regulating expression of the endogenous gene. As such it appears that random integration can occur with a construct comprising X and Y and a promoter. In light of the above considerations the specification does not support the claimed embodiments of a DNA construct having the sequence 5' A-P-B-Q-C 3'.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-24, 26-29, 32-34, and 41-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For clarity the aspects of the previous enablement rejection that are maintained are reiterated below.

The claims are directed to a method of inserting a heterologous gene coding sequence into an endogenous gene in a mouse embryonic stem cell genome and expressing said heterologous gene coding sequence, comprising the step of transforming the mouse cell with a random gene trap vector comprising a DNA construct, wherein the DNA construct lacks a promoter, and comprises the sequence 5' A-P-B-Q-C 3', in which P is an internal ribosome entry site (IRES); Q is the

heterologous gene sequence, including a translation start codon; and A, B and C are, separately, optional linked sequences. The claims are further directed to a mouse embryonic stem cell comprising a heterologous gene coding sequence inserted by the above method and a DNA construct, wherein the DNA construct comprises the sequence 5' A-P-B-Q-C 3' as above.

The specification has taught a DNA construct comprising the sequence 5' X-A-P-B-Q-C-Y 3', wherein X and Y comprise nucleotide sequences that are homologous to an endogenous gene in a mouse cell, P is an internal ribosome entry site (IRES); Q is the heterologous gene sequence, including a translation start codon; and A, B and C are, separately, optional linked sequences. The specification has also taught the creation of transgenic mice comprising the same construct, wherein the construct was introduced into ES cells to produce chimeric mice. However, the specification has not taught a DNA construct comprising the sequence 5' A-P-B-Q-C 3'. Moreover, the specification has not taught a method of inserting a heterologous gene coding sequence into an endogenous mouse cell genome using a DNA construct having the sequence 5' A-P-B-Q-C 3' or a mouse cell comprising a DNA construct having the sequence 5' A-P-B-Q-C 3'. The instant specification has not even provided a working example directed to a mouse cell transfected *in vitro* with the claimed DNA construct, 5' A-P-B-Q-C 3'. As such, in light of the teachings of the specification, which are directed to the creation of transgenic mice, there do not appear to be any other disclosed uses for the claimed DNA construct or method than for the creation of transgenic mice.

As a first issue, the instant specification has not provided any guidance that would enable the skilled artisan to practice the claimed invention. In particular, the construct embraced by the claims is not disclosed in the instant specification. More particularly, the claim limitations of a DNA construct comprising 5' A-P-B-Q-C 3' are not disclosed in the specification. As such the claimed construct has not been taught. Moreover, the skilled artisan would not know how to use the claimed invention because it has not been disclosed in the instant specification. The guidance and working examples provided by the instant specification are directed to making and using a different DNA construct. While the instant specification teaches the creation of transgenic mice, use of the claimed construct in that context has not been disclosed. However, if one of skill were contemplating the creation of transgenic mice with the claimed construct the issues of unpredictability related to such are discussed in on pages 11-12 of the Office action mailed on 7/5/02. See Wall and Houdebine. Given, the lack of guidance provided by the instant specification it would have required undue experimentation to use the claimed invention.

Claims 28-29 are directed to mouse embryonic stem cells comprising the DNA construct encompassed by the claims, having the sequence 5' A-P-B-Q-C 3'. The claims as written do not recite isolated cells, and can be interpreted to read on a transgenic mouse when taken with the teachings of the specification. However, as the instant specification has not taught the creation of a single transgenic mouse comprising the recited construct as mentioned above or a cultured cell comprising the recited construct the claims are not enabled.

Claims 22-24, 26-29, and 41 are directed to a method for inserting a heterologous gene coding sequence into an endogenous gene in a mouse cell genome and mouse cells produced by the method. The method requires inserting a heterologous gene coding sequence into an endogenous gene and is interpreted to read on insertion of a heterologous coding sequence by homologous recombination. The claims however do not require that the recited construct comprise sequences that are homologous to the endogenous gene sequence. As such it is unpredictable if the heterologous coding sequence can be inserted into an endogenous gene because heterologous gene sequences (for example, transgenes) unless specifically designed for homologous recombination will randomly integrate into a host genome. Random integration does not necessarily include integration into endogenous genes. See Wall and Houdebine on pages 11-12 of the Office action mailed on 7/5/02. If by chance random integration resulted in incorporation of the claimed construct into an endogenous gene, the specification has not provided any guidance for determining which endogenous gene has incorporated the claimed construct. More over the claims as written would require nothing more than trial and error experimentation to successfully introduce the claimed DNA construct into an endogenous gene. Given the lack of recited homologous sequences in the claims it would have required undue experimentation for one of skill in the art to insert a heterologous coding sequence into an endogenous gene in a mouse cell genome as claimed without a reasonable expectation of success.

Given the lack of guidance, relevant teachings, and the absence of working examples, it would have required undue experimentation for the skilled artisan to make and use the invention as claimed.

Applicant's arguments filed 12/10/02 have been fully considered but they are not persuasive. Applicants have argued that the claimed constructs and methods are fully supported by the instant applications and that a skilled person would be able to make the claimed constructs using standard genetic engineering techniques as the individual elements of the constructs are all well known. See the amendment on pages 6-7.

In response, the Examiner asserts that the instant specification has not taught the construct as claimed, having a sequence of 5' A-P-B-Q-C 3'. See the new matter rejection above. The Examiner maintains that the instant claims are not enabled because the specification does not teach how to make or use the construct as newly amended. The specification does not lead one of skill to make the construct in the method as claimed; therefore, the specification does not provide adequate guidance for one of skill to perform the method or teach how to use such a construct in the method claimed. The guidance and working examples provided by the instant specification are directed to making and using a different DNA construct. A mere argument that the claimed construct could be made and used by a skilled artisan since the components of the construct are known is not sufficient to enable the claims. If there is no disclosure of starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement

that cannot be rectified by asserting that all disclosure related to process is within skill of art. See Genentech Inc. v. Novo Nordisk A/S 42 USPQ2d 1001, 1997. In this case the starting material that has not been disclosed is the claimed construct, having the sequence 5' A-P-B-Q-C 3'.

Applicants have argued that the claimed invention is particularly useful because it can identify random integrations. Applicants further argue that if random integration does not insert the heterologous sequence within genes of a host cell, expression of the heterologous sequence is not observed. Applicants discuss that if integration does occur within an expressed host gene, the heterologous sequence can then be expressed in the host cell and can be identified/selected by virtue of its expression products. Applicants submit that selection/identification process would not involve undue experimentation. See pages 7-8 of the amendment.

In response, the Examiner maintains that it is unpredictable if a heterologous coding sequence can be inserted into an endogenous gene by random integration, which would require nothing more than trial and error experimentation. See pages 10-11 of the Office action mailed on 7/5/02. It is further maintained that unless a heterologous coding sequence is specifically designed for insertion into a heterologous gene coding sequence, for example by homologous recombination, such that it will contain regions homologous to endogenous sequences, it will be unpredictable if such a heterologous sequence can insert into an endogenous coding sequence as the means of integration is random. Moreover, the construct as claimed lacks a promoter, which means that the random integration event must allow for the construct to integrate into an

endogenous coding sequence such it is under the control of the promoter of the endogenous sequence and in-frame. Otherwise, it would appear that the heterologous sequence would not be expressed since it does not comprise a promoter sequence. The Examiner asserts that it is unpredictable if a heterologous gene can randomly integrate into an endogenous gene such that it's expression under control of the endogenous gene's promoter; to achieve such a goal requires trial and error experimentation. In addition, the evidence of record has not provided guidance for determining which endogenous gene has incorporated the claimed construct. To simply assert that integration can be identified by the expression products of the heterologous gene is not sufficient and does not explain how the endogenous gene comprising the heterologous gene can be identified and does not remove the issues of unpredictability of obtaining expression of the heterologous gene.

Applicants have also argued that working examples are not necessary to demonstrate that a construct, such as the claimed construct can be integrated into a host cell genome and successfully expressed. Applicants have pointed to pages 4-5 of the specification, in the background section, for support. See pages 8-9 of the amendment.

In response, the Examiner asserts that while working examples are not necessary the instant specification has failed to provide a correlation between the claimed construct and integration into the host cell genome, wherein subsequent to integration the heterologous coding sequence is expressed. Such a correlation may resolve issues of unpredictability with regard to random integration as discussed above.

Applicants have pointed to pages 4-5 of the specification for support of their arguments directed to the necessity of working examples. However, on page 4, at the bottom, of the specification it is clearly stated that a disadvantage of gene trap vectors used for random integration is that there is no control over the site of integration or the generation of endogenous gene/transgene fusion products. On page 5, at the bottom, the specification states that currently an efficient procedure by which a heterologous gene sequence can be inserted into the genome of a host cell such that expression of the heterologous gene in a desired pattern, wherein a desired pattern is intimately to couple expression of the heterologous gene with regulatory elements controlling expression of a targeted endogenous gene, does not exist. On page 6 of the specification, it is stated that an object of the invention is to provide a DNA construct and methods for its use that enable improved efficiency of the heterologous gene expression in a host cell, wherein the DNA construct has the sequence 5' X-A-P-B-Q-C-Y 3', and wherein X and Y are homologous to a host gene locus. As such, working examples exemplifying the claimed construct, having the sequence 5' A-P-B-Q-C 3' are necessary.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22-24, 26, 28-29, and 32-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Tessier-Lavigne et al (US 6,248,934). The previous rejection is maintained for the reasons of record advanced on pages 13-14 of the Office action mailed on 7/5/02. For clarity the rejection is reiterated below.

Tessier-Lavigne et al teach a DNA construct comprising the following elements from 5' to 3': a splice acceptor site, an IRES sequence, a heterologous nucleotide sequence, and a polyadenylation signal, wherein the construct is promoterless. See figure 1a, column 2 lines 25-31, and column 5 lines 29-33. Tessier-Lavigne et al also teach that the construct integrates into a gene in a cell, wherein the cells may be mouse embryonic stem cells. See columns 7-8 as well as the claims.

Applicant's arguments filed 12/10/02 have been fully considered but they are not persuasive. Applicants have submitted that US 6,248,934 is not prior art as the pending claims are fully supported by Applicants priority documents and are entitled to an effective filing date of no later than 21April 1994.

In response, the Examiner asserts that priority is denied to parent application 08/537,765 (see above) and that the effective filing date of the instant application is its actual filing date, which is 7 July 1999. As such US 6,248,934 is relevant as prior art and thus, anticipates the pending claims.

Accordingly, the rejection is maintained for the reasons of record.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

Art Unit 1632

MICHAEL WILSON
PRIMARY EXAMINER